Voranigo

Procedural steps taken and scientific information after the authorisation*

*Due to the Agency`s update of its procedure management systems, an additional document, reflecting the historical lifecycle may be available in the 'Assessment history' section. For the complete product lifecycle procedures, you may need to also refer to **EPAR - Procedural steps taken and scientific information after authorisation (archive)**.

Application number	Scope	Opinion/ Notification [1] issued on	Commission Decision Issued [2] / amended on	Product Information affected [3]	Summary
Variation type IB /	Outcome:	26/08/2026		SmPC	

[1] Notifications are issued for type I variations and Article 61(3) notifications (unless part of a group including a type II variation or extension application or a worksharing application). Opinions are issued for all other procedures.
[2] A Commission decision (CD) is issued for procedures that affect the terms of the marketing authorisation (e.g. summary of product characteristics, annex II, labelling, package leaflet). The CD is issued within two months of the opinion for variations falling under the scope of Article 23.1a(a) of Regulation (EU) No. 712/2012, or within one year for other procedures.
[3] SmPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

EMA/VR/0000362255	Q.II.f.1.b) Extension of the shelf life of the finished product - Q.II.f.1.b.5 Extension of the shelf life of the finished product based on extrapolation of stability data in accordance with relevant stability guidelines - Accepted				
Variation type II / EMA/VR/0000316249	Outcome: C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data - Accepted Update of section 4.4 and 4.8 of the SmPC in order to revise the information on hepatotoxicity and add blood bilirubin increased with common frequency, hepatic failure, autoimmune hepatitis, hepatic necrosis, all with uncommon frequency and drug-induced liver injury, and hepatitis acute with a not known frequency to the list of adverse drug reactions (ADRs) based on internal safety signal analyses; the Package Leaflet is updated accordingly. The MAH also took the occasion to update the list of local representative for Finland in the Package leaflet.	10/04/2026		SmPC and PL	SmPC new text: Drug-induced hepatotoxicity, including serious cases of hepatic failure, hepatic necrosis and hepatitis acute have been reported in patients treated with vorasidenib in the pivotal clinical study or in post-marketing experience. The median time to first event onset for AST and ALT increased (any grade) was 85.0 days (range: 14 – 451 days) and 57.0 days (range: 1 – 506 days). Each of the following adverse reactions, hepatic failure, hepatic necrosis and autoimmune hepatitis, was reported once with vorasidenib in the INDIGO study. Relevant ADRs are included with their relevant frequency in the list of adverse drug reactions. For more information, please refer to the Summary of Product Characteristics.
Variation type IB / EMA/VR/0000323236	Outcome: This was an application for a group of	27/02/2026		SmPC	

	variations. B.II.f.1.b Extension of the shelf life of the finished product - B.II.f.1.b.z Other variation - Accepted B.II.f) Stability - B.II.f.z Other variation - Accepted				
Variation type II / EMA/VR/0000314168	Outcome: This was an application for a group of variations. C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.13 Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority - Accepted C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.13 Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority - Accepted C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.13 Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority - Accepted A grouped application following post approval commitments from the initial MA procedure (PAM-REC) consisting of:	05/02/2026			Not applicable

	C.I.13: Submission of the final report AG881-PPK-EMA-QUERIES (NP43465) concerning joint population PK analysis of vorasidenib (AG-881) and its metabolite (AGI-69460). C.I.13: Submission of the final report AG881-C-004-PPK-ADO-EMA-PMR (NP43494) concerning vorasidenib PK predictions supporting the dose selection in the adolescent (12 to <18) patient population using the updated EMA popPK model. C.I.13: Submission of the final report AG881-ER-EMA-QUERIE (NP43487) concerning exposure-response analysis of vorasidenib (AG-881), metabolite (AGI-69460) and active moiety to address.				
Variation type IB / EMA/VR/0000307162	Outcome: C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.z Other variation - Accepted C.I.z - to submit an updated Environmental Risk Assessment and the results of the requested OECD 123 (low stirring) test to determine log Dow and pKa in response to the Post Approval commitment agreed during the initial procedure assessment.	19/11/2025			